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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,288	03/23/2004	Bengt Guss	GUSS3001D/JDB	1848

23364 7590 12/14/2005

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/806,288	Applicant(s) GUSS ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30 is/~~are~~ pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 is/~~are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendments

- 1) Acknowledgment is made of Applicants' amendments filed 09/15/05 and 07/21/05 in response to the non-final Office Action mailed 03/21/05. Applicants have amended the specification.

Status of Claims

- 2) Claims 31-35 have been canceled via the amendment filed 07/21/05.
Claim 30 has been amended via the amendment filed 07/21/05.
Claim 30 is pending and is under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the title made in paragraph 7 of the Office Action mailed 03/21/05 is withdrawn in light of Applicants' amendment to the title.
- 6) The objection to the specification made in paragraph 9(a) of the Office Action mailed 03/21/05 is withdrawn in light of Applicants' amendment to the specification.
- 7) The objection to the specification made in paragraph 9(b) of the Office Action mailed 03/21/05 is withdrawn in light of Applicants' amendment to the specification.
- 8) The objection to the specification made in paragraph 9(c) of the Office Action mailed 03/21/05 is withdrawn in light of Applicants' amendment to the specification.

9) The objection to the specification made in paragraph 9(d) of the Office Action mailed 03/21/05 is withdrawn in light of Applicants' amendment to the specification.

10) The objection to claim 30 made in paragraph 15 of the Office Action mailed 03/21/05 is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Withdrawn

11) The rejection of claim 30 made in paragraph 11 of the Office Action mailed 03/21/05 under 35 U.S.C. § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claim 30 made in paragraph 12 of the Office Action mailed 03/21/05 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

13) The rejection of claim 30 made in paragraph 14 of the Office Action mailed 03/21/05 under 35 U.S.C. § 102(b) as being anticipated by Palker *et al.* (*PNAS* 85: 1932-1936, 1988, already of record) as evidenced by McGuinness *et al.* (*Mol. Microbiol.* 7: 505-514, 1993, already of record), is maintained for reasons set forth therein and herebelow.

Applicants submit the following arguments: (a) Since in the scientific world "antibodies raised against" a certain protein means that an individual has been vaccinated or immunized with the pure protein in question, the antibodies which are produced by the individual are specific for just this injected protein. (b) The antibodies produced in Example 12 are raised against a *Staphylococcus epidermidis* polypeptide having fibrinogen binding activity and having the comparatively long amino acid sequence of SEQ ID NO 13 or a fusion protein comprising this amino acid sequence. (c) The fibrinogen binding site is much larger than the three amino acid epitope cited by the Office. This is evident from the later publication where the authors have tried to find shorter sequences that would be fibrinogen binding, but did not succeed to find any sequence shorter than 331 amino acids. Applicants state that they have enclosed a copy of the article

Infection and Immunity, vol. 66, no. 6, pp. 2666-2673. (d) One of the inventors has provided an article in *Cell*, vol. 115, 217-228, 2003, K. Ponnuraj *et al.* This article shows that it is highly unlikely or impossible to think that a tripeptide would have a fibrinogen-binding property. The function of the fibrinogen-binding polypeptide of this invention is too complex to be comprised of a tripeptide only.

Applicants' arguments have been carefully considered, but are not persuasive. First, no article from *Infection and Immunity*, vol. 66, no. 6, pp. 2666-2673 has been submitted to the Office. Applicants' arguments are pertinent to the function of the recited polypeptide. However, it should be noted that what are claimed are antibodies to a polypeptide of SEQ ID NO: 13. What is claimed is not a polypeptide of SEQ ID NO: 13 having fibrinogen binding activity. Whether or not the prior art tripeptide NNT has fibrinogen binding activity is not the issue. As clearly set forth at paragraph 14 of the Office Action mailed 03/21/05, the limitation in the claim, 'antibodies raised against', represents a process limitation in the product claim. When claims are product-by-process claims, these claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art antibodies differs from that of the instantly claimed antibodies. Contrary to Applicants' assertion, the limitation "antibodies raised against" is not limited to a meaning or interpretation that an individual has been vaccinated or immunized with the 'pure' protein in question, and the antibodies produced by the individual are specific for 'just this injected protein'. Antibodies 'raised against' the unpurified or non-isolated fibrinogen-binding polypeptide of SEQ ID NO: 3, as is present on the

surface of whole cells of *S. epidermidis*, anticipate the instant claim. Similarly, antibodies raised naturally in a human or non-human species against polypeptide of SEQ ID NO: 3 present on the cell wall of an infecting or colonizing *S. epidermidis* anticipate the claim. Irrespective of the process by which the prior art antibodies were raised, since these antibodies are specific to the NNT peptide epitope, these antibodies would be expected to recognize or bind to the instantly recited fibrinogen binding polypeptide of SEQ ID NO: 3, because the very same NNT peptide epitope is also present in the instantly recited SEQ ID NO: 13 at amino acid positions 329-331 of SEQ ID NO: 13. The fibrinogen binding activity is not a property of the claimed antibodies, but is a functional property of the recited polypeptide. Therefore, the prior art antibodies to the NNT-containing peptide are expected to necessarily bind to the instantly recited NNT epitope-containing polypeptide of SEQ ID NO: 13, irrespective of the polypeptide's fibrinogen binding activity. The rejection stands. In *Smithkline Beecham Corporation v. Apotex Corp.*, 403 F.3d 1328 (Fed. Cir. 2005), the Federal Circuit held that 'a product that existed in trace amounts, although unknown and undetected and unisolated, is inherently anticipated' and barred from the patent system after it is discovered. Antibodies themselves and the ability to generate such antibodies are inherent in a given species. See at 1329 and 1330.

Rejection(s) under 35 U.S.C § 102

14) Claim 30 is rejected under 35 U.S.C § 102(b) as being anticipated by Espersen *et al.* (*APMIS* 5: 471-478, 1990) as evidenced by Pei *et al.* (*Infect. Immun.* 67: 4525-4530, 1999) and Nilsson *et al.* (*Infect. Immun.* 66: 2666-2673, 1998).

It is noted that the collected antibodies claimed in the instant claim are antibodies that bind to or recognize a *S. epidermidis* polypeptide comprising the amino acid sequence of SEQ ID NO: 3, irrespective of by which process these antibodies are raised.

Espersen *et al.* taught pooled (i.e., collected) human serum, pooled human plasma, and purified human IgG, which similar to fibrinogen, inhibited or blocked the adherence of silicone catheter-binding *S. epidermidis* strains isolated from patients with plastic-related infections to fibrinogen (see abstract; Table 3; and pages 472, 475 and 476). The pooled human serum or plasma of the prior art is

expected to contain collected antibodies that bind to the instantly recited fibrinogen-binding polypeptide in light of what is known in the art. For instance, Pei *et al.* teach that antibodies that block the adherence of *S. epidermidis* to fibrinogen are antibodies against the fibrinogen binding protein (Fbe) of Nilsson *et al. Infect. Immun.* 66: 2666-2673, 1998. See pages 4525 and 4530 of Pei *et al.* Although Espersen *et al.* are silent about the amino acid sequence of the polypeptide having fibrinogen binding activity to be SEQ ID NO: 13, because of the silicone catheter-binding property of the prior art *S. epidermidis* strains (which is known to involve binding via fibrinogen) and the ability of the antibodies to block their adherence to fibrinogen, Espersen's *S. epidermidis* strains are viewed as inherently containing the fibrinogen binding polypeptide of SEQ ID NO: 13. The fact that Espersen's antibodies block the adhesion of *S. epidermidis* strains to fibrinogen suggests that these antibodies are directed to the fibrinogen-binding polypeptide of SEQ ID NO: 13.

The limitation 'raised against' in the claim represents a process limitation in the product claim. When claims are product-by-process claims, these claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. In the instant case, Applicants have not shown that the underlying structure of the prior art antibodies differs from that of the instantly claimed antibodies.

Claim 30 is anticipated by Espersen *et al.*

Relevant Prior Art

15) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Fischer (US 5,571,511) disclosed high-titer sera collected from rabbits immunized with a whole cell preparation of *S. epidermidis* (see lines 24-67 of column 6).

Remarks

16) Claim 30 stands rejected.

For clarity, it is suggested that Applicants include the limitation --of-- before the limitation 'SEQ ID NO: 13' in lines 4 and 5 of the claim.

17) Applicants' amendment necessitated the new ground(s) of rejection presented in this action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (571) 273-8300.

19) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1645

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER